PCT/EP2005/001114

US Appln. No.: US Filing Date:

To Be Assigned August 11, 2006

Case No.: ITR0073YP

Page No.:3

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions and listings of claims in the application:

Claim 1. (Original) A nucleic acid molecule comprising a sequence of nucleotides that encodes a CEA fusion protein, wherein the CEA fusion protein comprises a CEA protein or variant thereof, fused to a substantial portion of an immunoenhancing element selected from the group consisting of: DOM, FcIgG, CT, LTA, and LTB; and wherein the fusion protein is capable of producing an immune response in a mammal.

Claim 2. (Currently Amended) The nucleic acid molecule of claim 1, wherein the CEA protein is a human CEA protein or variant thereof or a rhesus monkey CEA protein or variant thereof.

Claim 3. (Canceled)

Claim 4. (Original) The nucleic acid molecule of claim 1, wherein the CEA protein is C-terminally truncated.

Claim 5. (Original) The nucleic acid molecule of claim 4, wherein the C-terminal truncation comprises amino acids 679 – 702 of SEQ ID NO:20.

Claim 6. (Canceled)

Claim 7. (Original) The nucleic acid molecule of claim 1, wherein the immunoenhancing element comprises a substantial portion of subunit B of heat labile enterotoxin of E. coli (LT).

Claim 8. (Original) The nucleic acid molecule of claim 7, wherein the LT subunit B is truncated of its signal sequence.

PCT/EP2005/001114

US Appln. No.: US Filing Date:

To Be Assigned August 11, 2006

Case No.: ITR0073YP

Page No.:4

Claim 9. (Canceled)

Claim 10. (Original) The nucleic acid molecule of claim 1, wherein the sequence of nucleotides comprises a sequence of nucleotides selected from the group consisting of SEQ ID NOs:7, 9, 11, 12, 14, 21, 25, 49, 50, and 52.

Claim 11. (Currently Amended) The nucleic acid molecule of claim 10 11, wherein the sequence of nucleotides comprises a sequence of nucleotides as set forth in SEQ ID NO:9, SEQ ID NO:11, or SEQ ID NO:12.

Claim 12. (Currently Amended) A The nucleic acid molecule of claim 1 comprising a sequence of nucleotides that encodes a CEA fusion protein, wherein the sequence of nucleotides is as set forth in SEQ ID NO:12.

Claim 13. (Original) The nucleic acid molecule of claim 8, wherein the C-terminal end of the CEA protein is fused to the N-terminal end of LT subunit B.

Claim 14. (Currently Amended) A vector comprising the nucleic acid molecule of claim 13 4.

Claim 15. (Original) The vector of claim 14, wherein the vector is an adenovirus vector or a plasmid vector.

Claim 16. (Currently Amended) The vector of claim 15, wherein the vector is of an adenovirus type selected from the group consisting of: Ad5, Ad6 and Ad24 vector.

Claims 17-19. (Canceled)

Claim 20. (Currently Amended) A host cell comprising the vector of claim 14 15.

Claim 21. (Original) A process for expressing a CEA fusion protein in a recombinant host cell, comprising:

PCT/EP2005/001114

US Appln. No.: US Filing Date:

To Be Assigned August 11, 2006

Case No.: ITR0073YP

Page No.:5

(a) introducing a vector comprising the nucleic acid molecule of claim 1 into a suitable host cell; and,

(b) culturing the host cell under conditions which allow expression of said human CEA fusion protein.

Claim 22. (Original) A purified CEA fusion protein encoded by the nucleic acid molecule of claim 1.

Claim 23. (Original) The purified CEA fusion protein of claim 22, wherein the fusion protein comprises a sequence of amino acids selected from the group consisting of: SEQ ID NOS:8, 10, 13, 15, 45, 46, 51, and 53.

Claim 24. (Original) A method of preventing or treating cancer comprising administering to a mammal a vaccine vector comprising the nucleic acid molecule of claim 1.

Claims 25-26. (Canceled)

Claim 27. (Currently Amended) A method according to claim 24 26 wherein the vector is an adenoviral vector comprising an adenoviral genome with a deletion in the adenovirus E1 region, and an insert in the adenovirus E1 region, wherein the insert comprises an expression cassette comprising:

- (a) a polynucleotide comprising sequence of nucleotides that encodes a CEA fusion protein, wherein the CEA fusion protein comprises a CEA protein or variant thereof, fused to a substantial portion of an immunoenhancing element selected from the group consisting of: DOM, FcIgG, CT, LTA, and LTB; and wherein the fusion protein is capable of producing an immune response in a mammal.; and,
 - (b) a promoter operably linked to the polynucleotide.

Claim 28. (Currently Amended) A method according to claim 24 26 wherein the vector is a plasmid vaccine vector, which comprises a plasmid portion and an expressible cassette comprising

(a) a polynucleotide comprising a sequence of nucleotides that encodes a CEA fusion protein, wherein the CEA fusion protein comprises a CEA protein or variant thereof, fused to a

PCT/EP2005/001114

US Appln. No.: To Be Assigned US Filing Date: August 11, 2006

Case No.: ITR0073YP

Page No.:6

substantial portion of an immunoenhancing element selected from the group consisting of: DOM, FcIgG, CT, LTA, and LTB; and wherein the fusion protein is capable of producing an immune response in a mammal.; and,

(b) a promoter operably linked to the polynucleotide.

Claim 29. (Original) An adenovirus vaccine vector comprising an adenoviral genome with a deletion in the E1 region, and an insert in the E1 region, wherein the insert comprises an expression cassette comprising:

- (a) a polynucleotide comprising a sequence of nucleotides that encodes a CEA fusion protein, wherein the CEA fusion protein comprises a CEA protein or variant thereof, fused to a substantial portion of an immunoenhancing element selected from the group consisting of: DOM, FcIgG, CT, LTA, and LTB; and wherein the fusion protein is capable of producing an immune response in a mammal.; and
 - (b) a promoter operably linked to the polynucleotide.

Claim 30. (Original) An adenovirus vector according to claim 29, wherein the vector is of an adenovirus type selected from the group consisting of Ad5, Ad6, and Ad24 which is an Ad 5 vector.

Claim 31. (Canceled)

Claim 32. (Original) A vaccine plasmid comprising a plasmid portion and an expression cassette portion, the expression cassette portion comprising:

- (a) a polynucleotide comprising a sequence of nucleotides that encodes a CEA fusion protein, wherein the CEA fusion protein comprises a CEA protein or variant thereof, fused to a substantial portion of an immunoenhancing element selected from the group consisting of: DOM, FcIgG, CT, LTA, and LTB; and wherein the fusion protein is capable of producing an immune response in a mammal; and,
 - (b) a promoter operably linked to the polynucleotide.

Claim 33. (Original) A method of treating a mammal suffering from or predisposed to a CEA-associated cancer comprising:

(a) introducing into the mammal a first vector comprising:

PCT/EP2005/001114 To Be Assigned

US Appln. No.: To Be Assigned US Filing Date: August 11, 2006

Case No.: ITR0073YP

Page No.:7

- (i) a polynucleotide comprising a sequence of nucleotides that encodes a CEA fusion protein, wherein the CEA fusion protein comprises a CEA protein or variant thereof, fused to a substantial portion of an immunoenhancing element selected from the group consisting of: DOM, FcIgG, CT, LTA, and LTB; and wherein the fusion protein is capable of producing an immune response in a mammal; and,
 - (ii) a promoter operably linked to the polynucleotide;
 - (b) allowing a predetermined amount of time to pass; and
 - (c) introducing into the mammal a second vector comprising:
- (i) a polynucleotide comprising a sequence of nucleotides that encodes a CEA fusion protein, wherein the CEA fusion protein comprises a CEA protein or variant thereof, fused to a substantial portion of an immunoenhancing element selected from the group consisting of: DOM, FcIgG, CT, LTA, and LTB; and wherein the fusion protein is capable of producing an immune response in a mammal; and
 - (ii) a promoter operably linked to the polynucleotide.

Claim 34. (Original) A method according to claim 33 wherein the first vector is a plasmid and the second vector is an adenovirus vector.

Claim 35. (Canceled)